

## REMARKS

Claims 1, 18, 20, 23, 24, 26, 28, and 31 are pending. Claims 23, 24, 26, and 31 are withdrawn. Claims 2-17, 19, 21, 22, 25, 27, 29, and 30 are canceled. Claim 1 has been amended.

### Amendments to the Specification

Paragraph [0014] has been replaced with a substitute paragraph to correct typographical errors.

Paragraph [0031] has been replaced with a substitute paragraph to correct a typographical error.

Paragraph [0042] has been replaced with a substitute paragraph to more accurately describe the corresponding drawing.

Paragraph [0044] has been replaced with a substitute paragraph to correct a typographical error, delete references to items that do not appear in the corresponding figures, introduce sequence identifiers into the drawings, and provide the long form for the abbreviations EGFP and CMV.

Paragraph [0054] has been replaced with a substitute paragraph to correct typographical errors.

Table 2A and its heading have been replaced with a substitute table and heading to corrects a typographical error and provide the long form for the GNAT1 gene.

The heading for Table 2B has been replaced with a substitute heading to correct a typographical error.

The heading for Table 2C has been replaced with a substitute heading to correct a typographical error.

Paragraph [0059] has been replaced with a substitute paragraph to correct a typographical error.

Paragraph [0095] has been replaced with a substitute paragraph to correct a typographical error.

Paragraph [0098] has been replaced with a substitute paragraph to correct typographical errors.

Table 1A and its heading have been replaced with a substitute table and heading to correct typographical errors.

Paragraph [0099] has been replaced with a substitute paragraph to correct a typographical error.

Paragraph [0100] has been replaced with a substitute paragraph to correct a typographical error.

The heading for Table 1B has been replaced with a substitute heading to correct a typographical error.

Paragraph [0104] has been replaced with a substitute paragraph to correct a typographical error.

Paragraph [0107] has been replaced with a substitute paragraph to correct a typographical error.

The heading for Example 5 has been amended to correct a typographical error.

Applicants believe no new matter has been added by these amendments.

Amendments to Drawings

Figure 3 has been amended to correct typographical errors and to provide more legible journal citations. Application submit herewith Formal Drawings to replace the present informal drawings.

Sequence Compliance

The Examiner objected to Figure 4 because it did not contain sequence identifiers. Accordingly, paragraph [0044] has been amended to insert the sequence identifiers for Figure 4.

Rejections Under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1, 18, 20, and 28 under 35 U.S.C. §112, second paragraph, for being indefinite for claiming RNAi as a compound. Applicants traverse the rejection to the extent is maintained over the claims as amended.

Applicants acknowledge that the acronym RNAi has more than one definition in the art, for example, “RNA interference” which refers to the process, and “interfering RNA”, which refers to the compound. Applicants submit that paragraph 3 of the Specification provides a definition of RNAi as pertaining to “interfering RNA”. However, depending upon the context in the Specification and Claims, RNAi could have either definition; which definition applied would be easily discernable to one skilled in the art. For example, “RNAi” refers to the compound, in the claims presently under consideration.

Rejections Under 35 U.S.C. §102(a) over Yu et al. (2002) Proc. Natl. Acad. Sci. USA 99:6047-52

The Examiner rejected claims 1, 18, 20, and 28 under 35 U.S.C. §102(a) as being anticipated by Yu et al. (2002) Proc. Natl. Acad. Sci. USA 99:6047-52 (“Yu et al.”). Applicant traverses the rejection to the extent it is maintained over the claims as amended.

Applicants submit that Yu et al. discloses polynucleotides comprising RNAis driven only by U6 promoters. Yu et al. does not disclose a polynucleotide comprising an RNAi driven by a tissue specific promoter, a cell specific promoter, and/or an inducible promoter, further

comprising a cleaving element capable of cleaving the nucleotide sequence 5' and/or 3' to the RNAi. Applicants therefore respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §102(e) over Engelke et al. (US 2003/0148519)

The Examiner rejected claims 1, 18, 20, and 28 under 35 U.S.C. §102(e) as being anticipated by Engelke et al. (US 2003/0148519) ("Engelke et al."). Applicant traverses the rejection to the extent it is maintained over the claims as amended.

Applicants submit that Engelke et al. does not disclose a polynucleotide comprising an RNAi driven by a tissue specific promoter, a cell specific promoter, and/or an inducible promoter, *further comprising* a cleaving element capable of cleaving the nucleotide sequence 5' and/or 3' to the RNAi. Applicants therefore respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §102(e) over Fire et al. (US 6,506,559 B1)

The Examiner rejected claims 1 and 28 under 35 U.S.C. §102(e) as being anticipated by Fire et al. (US 6,506,559 B1) ("Fire et al."). Applicant traverses the rejection to the extent it is maintained over the claims as amended.

Applicants submit that Fire et al. does not disclose a polynucleotide comprising an RNAi driven by a tissue specific promoter, a cell specific promoter, and/or an inducible promoter, *further comprising* a cleaving element capable of cleaving the nucleotide sequence 5' and/or 3' to the RNAi. Applicants therefore respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §102(e) over Graham et al. (US 6,573,099 B2)

The Examiner rejected claims 1, 18, 20, and 28 under 35 U.S.C. §102(e) as being anticipated by Graham et al. (US 6,573,099 B2) ("Graham et al."). Applicant traverses the rejection to the extent it is maintained over the claims as amended.

Applicants submit that Graham et al. does not disclose a polynucleotide comprising an RNAi driven by a tissue specific promoter, a cell specific promoter, and/or an inducible

promoter, *further comprising* a cleaving element capable of cleaving the nucleotide sequence 5' and/or 3' to the RNAi. Applicants therefore respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §103(a)

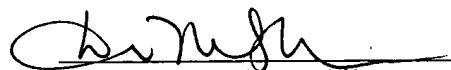
The Examiner rejected claims 1, 18, 20, and 28 under 35 U.S.C. §103(a) as being unpatentable over Elbashir et al. (2001) Nature 411: 494-498 ("Elbashir et al."), in view of Tuschl et al. (WO 02/44321) ("Tuschl et al.") and Luo et al. (US 6,211,164 B1) ("Luo et al."). Applicant traverses the rejection to the extent it is maintained over the claims as amended.

Applicants submit that Elbashir et al. discloses polynucleotides comprising RNAis driven only by SV40 or thymidine kinase promoters. Tuschl et al. also only discloses SV40 or thymidine kinase promoters. Neither Elbashir et al. nor Tuschl et al. disclose a polynucleotide comprising an RNAi driven by a tissue specific promoter, a cell specific promoter, and/or an inducible promoter, *further comprising* a cleaving element capable of cleaving the nucleotide sequence 5' and/or 3' to the RNAi. Luo et al. does not complement the deficiency in these references by disclosing a cleaving element capable of cleaving the nucleotide sequence 5' and/or 3' to the RNAi. Applicants therefore respectfully request that the rejection be withdrawn.

Applicants believe no new matter has been added by these amendments.

Respectfully submitted,

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